# How CBER Communicates

Mary Meyer, Director

Office of Communication, Training and Manufacturers Assistance

# Commissioner's Priorities

- Strong FDA
- Risk Management
- Decrease Medical Errors and AEs
- Better informed constituents
- Counter-terrorism

***All highly pertinent to CBER's missions and product regulation***

# How CBER Communicates

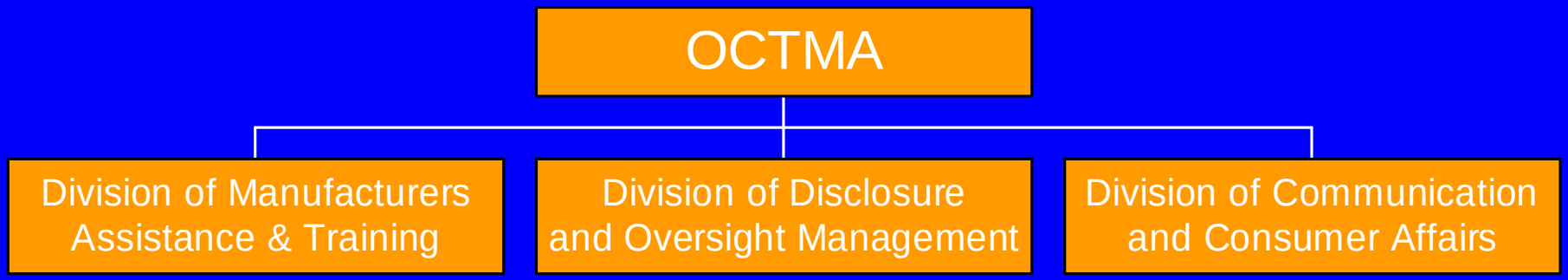
- Public Meetings, Workshops, Speakers
- Exhibit Program
- FOIA
- GGP's
- SOPP's
- Advisory Committees – 1-800-741-8138
- Ombudsman – (301) 827-0379

# Office of Communication, Training & Manufacturers Assistance

Maintain effective channels of internal and external communication

- Provide assistance to manufacturers & scientific associations to promote understanding of compliance with FDA regulations
- Direct CBER's consumer and professional information activities in coordination with other Agency components
- Responsible for activities relating to the administration of the Center's Document Control Center

# OCTMA Organization



# Division of Manufacturers Assistance and Training

- Provide Assistance to Industry and Trade Associations
- Access to New Policy, Guidance Documents, General Information.
  - 1-800-835-4709
  - MATT@CBER.FDA.GOV
- Coordinate with external organizations to develop & implement training, professional & technical development

# Division of Disclosure & Oversight Management

- Responds to Freedom of Information Act & Privacy Act requests
- Serves as CBER's liaison for GAO and HHS OIG oversight activities
- Develops responses to congressional requests, including proposed legislation
- Coordinates Center activities related to litigation, tort claims and third party subpoenas

# Division of Communication and Consumer Affairs

- Develops information on biological products for health professionals and consumers
  - Responds to inquiries from the public
  - 1-800-835-4709
  - OCTMA@CBER.FDA.GOV
- Manages content development, design, policies for CBER's Website
- Manages automated email/listserv

# Exhibit Program

- Launched in CY 2000
- Target Audiences Industry, Clinical Researchers, Healthcare Providers
- CY 2001 – Exhibits at 8 meetings
- CY 2002 – Exhibits at 12 meetings
- CY 2003 – Exhibits at 13 meetings

***Joint effort with program offices - Very well-received by audiences***

# CBER's Website
# Organization of Information

- Product Category - Blood, Therapeutics, Vaccines, Cellular & Gene Therapy, Allergenics, Tissue, Devices
- Information Category - Products, EFOI Reading Room, Meetings, Research, About Us
- Special Interest - Manufacturers, Health Care Professionals, Consumers
- Other Major Areas – Recalls, Safety, Guidances, Bioterrorism

# Section 8100 Communication

- 8101.1 - Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Applicants
- 8101.2 – Scheduling and Documentation of Liaison Meetings
- 8104 – Documentation of Telephone Contacts with Regulated Industry

# Document Control Center

- Provides life cycle records management
  - Submission, review, post review, inactive storage, final disposition
- SOPP's for submission of regulatory documents
  - 8007 – Binding Procedures for Regulatory Documents
  - 8110 – Investigational and Marketable Applications
- Activities
  - Mail & courier services: over 1.3 million pieces
  - CBER staff are in multiple locations
  - Log, process, distribute BLAs, Supplements, INDs, PMAs, 510(k)s, MFs, NDAs

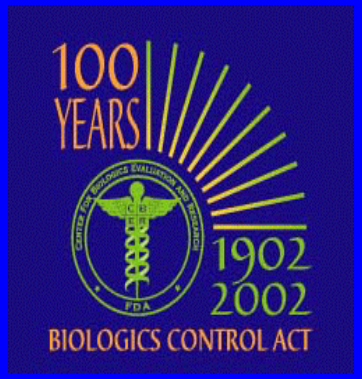
# Communication Stats

- Internet – 2,500,000 hits per month
- Automated Email – 8500 subscribers to 3 listservs (CBERINFO, BLOODINFO, FPRECALLS)
- Hard Copy – 1200 documents, 30 sent/month
- Telephone – 800 calls/month
- Public Email Accounts – 600 emails/month

# Contacting CBER

- CBER is available
  - Phone: 1-800-835-4709
  - Email: MATT@CBER.FDA.GOV
  - Internet: www.fda.gov/cber/
  - Automated email service
  - Ombudsman (HFM-4)
- Mailing Address:

  CBER
  Food and Drug Administration
  1401 Rockville Pike
  Rockville, MD 20852-1448

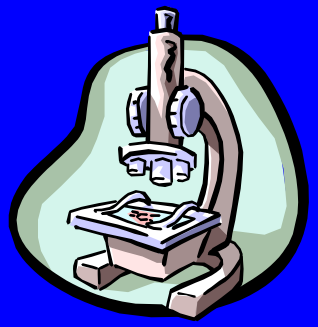


# Shepherding Safe and Effective Products

**Regulatory Research**

**FDA**

**Bench** **Bedside** **Marketplace**



**Translational Research**

**NIH**
**Academia**
**Industry**

**Pharmaceutical Research**

**Industry**

**BASIC** **APPLIED** **SAFETY & QUALITY**